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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/581,511 | 10/06/2000 | Raymond Andersen | P108281-0000 | 6795 |

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EXAMINER

LUKTON, DAVID

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 02/20/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/581,511 | Andersen |
| | Examiner David Lukton | Art Unit 1653 |
|  | | |
| <i>-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --</i> | | |
| Period for Reply | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>1</u> MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. | | |
| <ul style="list-style-type: none"> - Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | |
| Status | | |
| 1) <input checked="" type="checkbox"/> Responsive to communication(s) filed on <u>Jan 18, 2002</u> | | |
| 2a) <input type="checkbox"/> This action is FINAL . 2b) <input checked="" type="checkbox"/> This action is non-final. | | |
| 3) <input type="checkbox"/> Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> 1035 C.D. 11; 453 O.G. 213. | | |
| Disposition of Claims | | |
| 4) <input checked="" type="checkbox"/> Claim(s) <u>1-21</u> is/are pending in the application. | | |
| 4a) Of the above, claim(s) <u>19-21</u> is/are withdrawn from consideration. | | |
| 5) <input type="checkbox"/> Claim(s) _____ is/are allowed. | | |
| 6) <input type="checkbox"/> Claim(s) _____ is/are rejected. | | |
| 7) <input type="checkbox"/> Claim(s) _____ is/are objected to. | | |
| 8) <input checked="" type="checkbox"/> Claims <u>1-18</u> are subject to restriction and/or election requirement. | | |
| Application Papers | | |
| 9) <input type="checkbox"/> The specification is objected to by the Examiner. | | |
| 10) <input type="checkbox"/> The drawing(s) filed on _____ is/are objected to by the Examiner. | | |
| 11) <input type="checkbox"/> The proposed drawing correction filed on _____ is: a) <input type="checkbox"/> approved b) <input type="checkbox"/> disapproved. | | |
| 12) <input type="checkbox"/> The oath or declaration is objected to by the Examiner. | | |
| Priority under 35 U.S.C. § 119 | | |
| 13) <input type="checkbox"/> Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d). | | |
| a) <input type="checkbox"/> All b) <input type="checkbox"/> Some* c) <input type="checkbox"/> None of: | | |
| 1. <input type="checkbox"/> Certified copies of the priority documents have been received. | | |
| 2. <input type="checkbox"/> Certified copies of the priority documents have been received in Application No. _____. | | |
| 3. <input type="checkbox"/> Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). | | |
| *See the attached detailed Office action for a list of the certified copies not received. | | |
| 14) <input type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e). | | |
| Attachment(s) | | |
| 15) <input type="checkbox"/> Notice of References Cited (PTO-892) | | |
| 16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | | |
| 17) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ | | |
| 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ | | |
| 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) | | |
| 20) <input type="checkbox"/> Other: _____ | | |

Applicants' election of Group I with traverse is acknowledged. Claims 19-21 are withdrawn from consideration. Upon reconsideration, the restriction is revised. First, however, the following subgenera are defined:

G1: variable "Y" is C₁-C₆ unsaturated alkyl; the unsaturated alkyl group is optionally substituted as the claims permit;

G2: variable "Z" is any of the following: OH, OR, SH, SR, NH₂, NHCH(R₁₁)-COOH or NRCH(R₁₁)-COOH ;

G3: variable "Y" is C₁-C₆ saturated alkyl; the saturated alkyl group is optionally substituted as the claims permit;

G4: variable "Z" can be whatever the claims permit, provided that G2 is excluded;

G5: "R" is a "skeleton" which contains "zero" nitrogen atoms, but may be substituted as the claims permit;

G6: "R" is a "skeleton" which contains at least one nitrogen atom, and may be substituted as the claims permit

Restriction to one of the following inventions is required under 35 U.S.C. §121 (the numbering starts with Roman numeral "V", to avoid any redundancy):

V. Claims 1-18, drawn to compounds, limited to G1 and G2.

VI. Claims 1-7, 11-17, drawn to compounds, limited to G1 and G4.

VII. Claims 1-9, 11-17, drawn to compounds, limited to G2 and G3; substituent variable "R" can vary as the claims permit.

VIII. Claims 1-7, 11-17, drawn to compounds, limited to G3, G4 and G5.

IX. Claims 1-7, 11-17, drawn to compounds, limited to G3, G4 and G6.

The claimed inventions are distinct. The structures differ, and one can expect the physical and biological properties to differ. Notwithstanding the foregoing, in the event that claims are found allowable, the corresponding method-of-making claim will be rejoined for further examination.

*

Applicants have argued that they enjoy "immunity" from restriction, because they have previously filed a PCT application. However, applicants are not correct. Consider the following passage (MPEP 1850)

PCT Rule 13.2, as it was modified effective 01 July 1992, no longer specifies the combinations of categories of invention which are considered to have unity of invention. Those categories, which now appear as a part of Annex B to the Administrative Instructions, has been substituted with a statement describing the method for determining whether the requirement of unity of invention is satisfied.

Unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more special technical features. The term "special technical features" is defined as meaning those technical features that define a contribution which each of the inventions considered as a whole, makes over the prior art.

The determination is made based on the contents of the claims as interpreted in light of the description and drawings. Annex B also contains examples concerning unity of invention.

Independent and Dependent Claims.

Unity of invention has to be considered in the first place only in relation to the independent claims in an international application and not the dependent claims. By "dependent" claim is meant a claim which contains all the features of another claim and is in the same category

of claim as that other claim (the expression "category of claim" referring to the classification of claims according to the subject matter of the invention claimed for example, product, process, use or apparatus or means, etc.).

If the independent claims avoid the prior art and satisfy the requirement of unity of invention, no problem of lack of unity arises in respect of any claims that depend on the independent claims. In particular, it does not matter if a dependent claim itself contains a further invention. Equally, no problem arises in the case of a genus/species situation where the genus claim avoids the prior art. Moreover, no problem arises in the case of a combination/subcombination situation where the subcombination claim avoids the prior art and the combination claim includes all the features of the subcombination.

If, however, an independent claim does not avoid the prior art, then the question whether there is still an inventive link between all the claims dependent on that claim needs to be carefully considered. If there is no link remaining, an objection of lack of unity (that is, arising only after assessment of the prior art) may be raised. Similar considerations apply in the case of a genus/species or combination/subcombination situation.

As it happens, the claimed genus encompasses many known peptides, and peptidomimetic compounds. Undoubtedly, there are many novel compounds with the genus, particularly within Group V. In the event that a valid §102 or §103 rejection is applied against the genus as a whole, the question of multiple inventions versus one invention can again be revisited. If there is just one invention, then the §102 or §103 rejection would be applicable against all embodiments. Alternatively, if there are in fact multiple inventions, then the reference would not be applicable against all embodiments.

Consider the case where variable "R1" is "R". As it happens, variable "R" includes peptides. To illustrate, suppose one began with the following simple branched alkane: 2, 4, 6-trimethyl heptane. This can be represented as follows:



If one were to then introduce two nitrogen atoms, and to substitute with -NH₂, one would obtain the following:



If one were to then substitute three of the carbon atoms with oxo, one would obtain the following:



The resulting moiety is the tripeptide Ala-Ala-Ala. At this point, any of the side chains of the alanines could be "substituted" with a group such as carboxyl, hydroxyl or -SH.

Similarly, at the C-terminal end of the structure of formula I variable, R₉ is present. Suppose that variable "Y" represents methylene. Then variable R₉ is the following:



Again, variable "R" can be a peptide; in addition, variable "Y" is not confined to methylene; it could represent, for example, the amino acid valine (minus the amino and carboxyl groups) or it could represent serine (minus the amino and carboxyl groups), etc.

Applicant is advised that for the response to this requirement to be complete, an election of the invention to be examined must be indicated, even if the requirement is traversed (37 C.F.R. 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

Presumably, applicants will elect Group V. However, in the event that applicants elect a group other than Group V, a new species election will be required.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a generic claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

Should applicant traverse on the ground that the species are not patentable distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. §103 of the other invention.

*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton. Phone: (703) 308-3213.

An inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



DAVID LUKTON
PATENT EXAMINER
GROUP 1600